

4179-128

### Section III (Remarks)

#### A. Summary of Amendments

By the present amendment, paragraph [0022] of the specification has been amended, to appropriately update the status of U.S. Patent Application No. 09/977,644, which has issued as U.S. Patent No. 6,712,832. Further by the present amendment, claims 1-73 have been cancelled and claims 74-108 have been added, such that claims 74-108 are currently pending. No new matter within the meaning of 35 U.S.C. 132 has been introduced by virtue of such amendments.

#### B. Rejections Under 35 U.S.C. § 112

In the September 8, 2006 Office Action, claims 20-35 and 56 were rejected under 35 U.S.C. 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claimed the subject matter which applicant who regards as the invention. Specifically, claim 20 was rejected as indefinite due to the use of "(s)" in the term "layer(s)," and claim 20 was further rejected as indefinite due to the use of "arranged" in line 7 as requiring clarification of what is arranged for contact with introduced liquid. Claim 20 has been cancelled herewith, and the objectionable language is not contained in any of the pending claims 74-108. Accordingly, the rejections under 35 U.S.C. 112 are moot.

#### C. Rejections Under 35 U.S.C. § 103

In the September 8, 2006 Office Action, claims 20-35 and 47-56 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,976,950 to Connors et al. ("Connors"). All of claims 20-35 and 47-56 have been cancelled herewith, so their rejection under 35 U.S.C. § 103(a) is moot.

#### D. Patentable Distinctions of New Claims 74-108 Over the Cited Art

A discussion of the cited art is provided below, followed by identification of patentable distinctions of new claims 74-108 over the art cited in the September 8, 2006 Office Action.

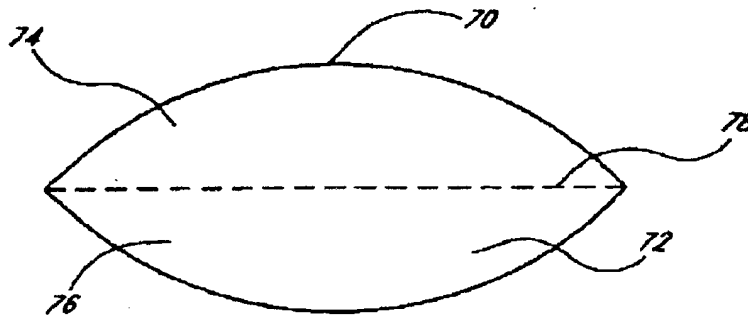
##### 1. Disclosure of Connors

Connors discloses various methods and apparatuses for attenuating or baffling transient pressure waves in various organs and systems of the body, including cardiovascular, pulmonary,

4179-128

renal/urological, gastrointestinal, hepatic/biliary, gynecological, central nervous, musculoskeletal, otorhinolaryngical and ophthalmic organs and systems. Connors, col. 1, lines 17-25. Preferred aspects are directed to treatment of disorders of the urinary tract caused by sudden fluctuations of intravesical pressure, to ameliorate symptoms and discomfort associated with incontinence, urgency, frequency, interstitial cystitis, irritable bladder syndrome and neurogenic bladders. Id., lines 26-34.

Connors describes a device having a compressible element that is placed within the human the urinary bladder, in a manner that allows the compressible element to act as a pressure accumulator or attenuator or to attenuate transient pressure events. Id., col. 9, lines 40-43 & col. 10, lines 48-50. An inflatable container includes a flexible wall that contains a compressible media such as a gas. Id., col. 11, lines 6-31. A flexible wall comprises first and second components bonded together along a seam. Id., col. 11, lines 28-32. Various sealing techniques, such as ultrasonic, radiofrequency, adhesive, or heat sealing, may be used. Id., col. 13, lines 12-15. One example of such a device is illustrated at Figure 5A of Connors, as reproduced below.



**FIG. 5A**

Referring to Figure 5A, the first component 74 and second component 76 are bonded together along a seam 78 formed on the outer periphery of the inflatable attenuation device 68. Id., col. 11, lines 28-40. The resulting structure illustrated in Figure 5A resembles a pillow.

4179-128

Connors refers to various methods of forming multi-layer materials for such attenuation devices, including "extrusion to prepare sheets, plugs, or tubular structures" (e.g., col. 16, line 63 – col. 17, line 7; col. 19, lines 27-29); "injection mold[ing] to fabricate intricately designed parts," (col. 19, lines 29-30); "compression mold[ing] to prepare films" (col. 19, lines 30-31); "dip-molded or extruded" (col. 22, lines 41-43); or "lamination, coextrusion, ... [or] spray molding" (col. 23, lines 62-67).

Connors teaches a variety of device shapes, as indicated by the following passages reproduced below:

The devices used in embodiments of the present invention may take many shapes. In some instances it may be desirable for manufacturing purposes to have the shape resemble dip-molded devices like condoms, surgical glove fingers, or children's toys. However, many other forms may provide better performance, in particular for providing baffling of pressure waves as well as attenuation of pressure spikes. Possible shapes for the attenuation devices include torroid like shapes, similar in form but not size to donuts and inner tubes; spoked wheel forms; horseshoe-like forms; mushroom-like forms; and banana-like forms.

(Col. 22, lines 29-40.)

FIG. 16A illustrates a toroidal embodiment, in which a plurality of central spokes are provided. FIG. 16B illustrates a crescent or "C" shaped attenuation device. Any of a variety of spherical, oval, elliptical or other shapes may be utilized such as those illustrated in FIG. 16C, in which the greatest length dimension of the inflated attenuation device is within the range of from about 1 to about 5 times the smallest cross-section. FIG. 16D illustrates a less arcuate variety as shown in FIG. 16B. In general, the attenuation device 66 may take any of a variety of forms which provides a sufficient volume to achieve the desired attenuation function, and which will minimize or eliminate risk of loss or obstructing outflow through the urethra.

(Col. 24, lines 14-26.)

Connors discloses that attenuation devices may contain various effervescent materials, whether loose or compartmentalized and separated within the device by a "separation wall," "crease," or "peelable bond, fold, or the like" (Connors, col. 32)

4179-128

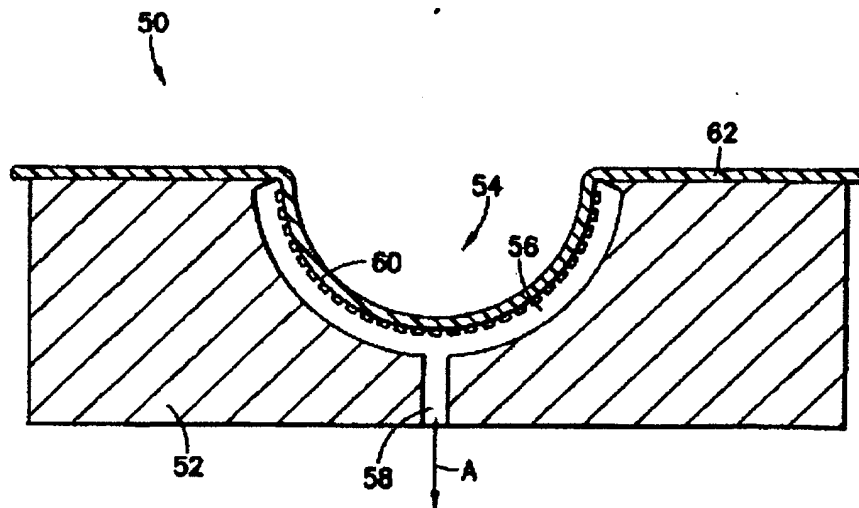
2. Patentable Distinctions of Amended Claims Over Connors

Claims 74-106 comprise two independent claims, namely, claims 74 and 95. Such claims recite, *inter alia*:

**“a balloon ... formed from two vacuum thermoformed half-sections of a multilayer film... , wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam ... .”**

(Emphasis added.) Nothing in Connors teaches or remotely suggests the use of vacuum thermoforming for producing half-sections, let alone the use of a thermoforming die having a substantially non-planar surface. To the contrary, Connors mentions a laundry list of other processes (including extrusion, injection molding, compression molding, dip-molding, lamination, coextrusion, and spray molding) but *fails to mention* any sort of vacuum thermoforming process.

As illustrated in Figure 3 of the instant patent application, vacuum thermoforming employs a die (whether male or female) including a surface (e.g., a non-planar surface) defining various gas withdrawal passages in communication with a vacuum source.

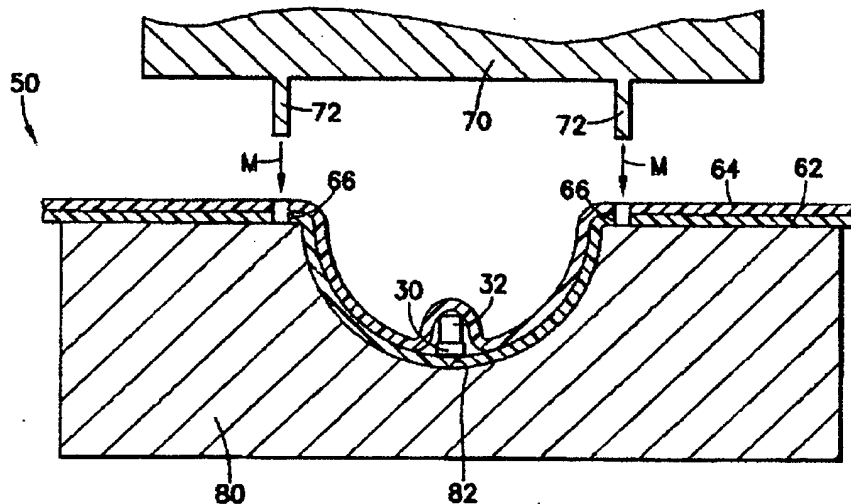


**FIG.3**

4179-128

Under negative pressure imposed by the vacuum source, a multilayer film 62 is drawn against the die cavity surface 60, and the evacuated gas is discharged from the die via the discharge passage 58 in the direction indicated by arrow A. Heat is then applied to a laminate film 62 comprising a thermoplastic polymer layer to raise its temperature above the softening temperature of the thermoplastic polymeric material.

**Vacuum thermoforming is advantageous to form non-planar (e.g., substantially hemispherical) half-sections with materials that are relaxed in such conformation. When two vacuum thermoformed non-planar half-sections are thereafter bonded along peripheral portions thereof (as illustrated below), the resulting balloon structure is substantially free of any seam stresses.**



**FIG. 4**

Upon inflation of the balloon produced according to the vacuum thermoforming process employed in the present invention, **undesirable pillowing or pinching along the seam joining the two half-sections is eliminated. This is in sharp contrast to the pronounced pillowing depicted in Connors Fig. 5A, as reproduced hereinabove.** Moreover, the thermoforming process can be completed in advance of the bonding step, such that heating of an effervescent material 32 positionable within the balloon can be avoided.

4179-128

Connors discloses a variety of manufacturing processes, but unmistakably fails to teach or remotely suggest vacuum thermoforming, let alone such process utilizing a die having a substantially non-planar surface, to yield half-sections of a balloon. Accordingly, for at least the reason that Connors fails to teach all of the features of the claims (e.g., as required by MPEP § 2143.03 to support a *prima facie* case of obviousness), claims 74 and 95 and the claims depending therefrom (*i.e.*, all pending claims) are non-obvious and patentably distinct over Connors.

The dependent claims recite further features that distinguish Connors.

For example, claims 75 and 96 further specify that the resulting half-sections in one embodiment are substantially hemispherical; Connors discloses no vacuum thermoformed substantially hemispherical half-sections.

In another example, claims 80, 81, 100, and 101 recite an effervescent material conformations that are not taught by Connors. While Connors refers generally to an effervescent material within an attenuation device, whether loose or compartmentalized and separated within the device by a "separation wall," "crease," or "peelable bond, fold, or the like" (Connors, col. 32), Connors fails to teach or suggests the claimed orientations of effervescent material, which orientations are desirable for compactly wrapping the balloon around the material for esophageal insertion into a patient and desirable for low-stress balloon inflation.

In yet another example, the therapeutic coatings of claims 91, 92, 103, and 104 are not believed to be disclosed by Connors.

E. (No) Fee Payable for Added Claims

By virtue of the present amendment, two (2) independent claims and thirty-one (31) total claims are pending in the application. Claim fees corresponding to five (5) independent claims and fifty-six (56) total claims were previously paid, *i.e.*, with the Preliminary Amendment filed on October 13, 2005 and the Application as filed on April 1, 2004. Accordingly, it is believed that no claim fees are due and payable in connection with the present amendment.

4179-128  
RECEIVED  
CENTRAL FAX CENTER

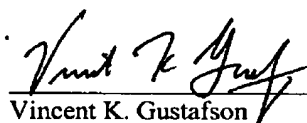
NOV 21 2006

**CONCLUSION**

Claims 74-108 as provided herein are fully patentably distinguished over the art and in allowable condition. Favorable examination of these claims and issuance of a notice of allowance thereon is requested.

If any issues remain outstanding, incident to the formal allowance of the application, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss their resolution, in order that this application may be passed to issue without delay.

Respectfully submitted,



Vincent K. Gustafson  
Reg. No. 46,182  
Attorney for Applicant

INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW  
Phone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File No.: 4179-128

The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284